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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,192

Applicant(s)

TARABISHY, IMAD ED.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 8, 10, and 11 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 9 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>April 27, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's cancellation of claim 6 in the reply filed on April 27, 2005 is acknowledged.
2. Applicant's amendment of claims 1, 2, 8, 10, and 11 in the reply filed on April 27, 2005 is acknowledged.

Claim Objections

3. Claim 1, 2, 8, and 11 are objected to because of the following informalities:
 - a. Regarding each of claims 1, 2, and 8, please substitute "with said interior" (see line 3) with -- within said interior--. Appropriate correction is required.
 - b. Regarding claim 11, please delete "said shaft further comprising," (see line 2). Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DeCarlo, Jr. (US 4,524,467 A; previously cited in PTO-892).

Referring to Figures 1-3, 10, and 11 (particularly Figure 10), DeCarlo, Jr. discloses a joint prosthesis comprising:

- (i) a segmented shell (body portion 64) having an interior surface (see Figures 1 and 10);
- (ii) a second shell (retaining ring portion 74) fixedly retained with said interior surface of said segmented shell;
- (iii) a cup (socket bearing 12), having an exterior surface *sized and configured to be fixedly retained* (emphasis added to functional language) in said second shell; and
- (iv) a shaft (body 18) having a first end and a second end, said first end of said shaft having a ball (ball 10) formed thereon that is received by said cup (socket bearing 12) *for movement therein* (emphasis added to functional language).

Response to Arguments

6. Applicant's arguments filed April 27, 2005 have been fully considered but they are not persuasive. Applicant argues that DeCarlo, Jr. '467 does not disclose/show a cup and/or a second shell. Examiner respectfully disagrees. Several dictionaries (i.e. Merriam-Webster online dictionary; www.dictionary.com) define "shell" as: "An external case or outside covering", "A framework or exterior structure". As noted above (102(b) rejection), the Examiner considers body portion 64 as the segmented shell, retaining ring portion 74 as the second shell, and socket bearing 12 as the cup. Each of body portion 64 and retaining ring portion 74 is segmented. As shown in Figures 2, 3, and 11, retaining ring portion 74 is fixedly retained with the interior surface of body portion 64, and socket bearing 12 is *sized and configured to be fixedly retained* (emphasis added to functional language) in retaining ring portion 74.

7. Claims 1, 5, and 8 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hyde, Jr. (US 6,589,281 A; previously cited in PTO-892).

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Referring to Figures 20-22 (see column 20, line 40 to column 21, line 40), Hyde, Jr. discloses a joint prosthesis comprising:

- (i) a segmented shell (base 195 comprises segments 194 and/or 196) having an interior surface (see Figures 21 and 22);
- (ii) a second shell (acetabular assembly 191) fixedly retained with said interior surface of said segmented shell and comprising a plurality of segments (modules/segments 192);
- (iii) a cup (cup 193), having an exterior surface *sized and configured to be fixedly retained* (emphasis added to functional language) in said second shell; and
- (iv) a shaft having a first end and a second end, said shaft comprising a body (core implant module 182 and/or modular stem 150), a neck (neck 184) attached to said body, and a ball (head 183) attached to said neck at said first end of said shaft, said ball received by said cup *for movement therein* (emphasis added to functional language).

Hyde, Jr. discloses (see column 20, line 40 to column 21, line 40) the structure of the second shell (acetabular assembly 191) as claimed in claim 8. It should be noted that several dictionaries (i.e. Merriam-Webster online dictionary; www.dictionary.com) define “shell” as: “An external case or outside covering”, “A framework or exterior structure”.

Response to Arguments

8. Applicant's remarks filed April 27, 2005 indicated: “Claims 2 and 8 have been amended to place these claims in independent form. As the examiner indicated that these claims would be allowable if placed in independent form, claims 2 and 8 are now in condition for allowance”.

Examiner respectfully disagrees. The Office Action of January 27, 2005 indicated dependent claims 2-4, 8, 9, and 12 as “objected to as being dependent upon a rejected base claim, but would

be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.” Claim 8, as currently amended, does not include all of the limitations of base (independent) claim 1 and intervening (dependent) claim 6.

9. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Afriat et al. (WO 01/35873 A1; also published as US 6,811,569 B1).

Referring to Figures 1-3, Afriat et al. disclose a joint prosthesis comprising:

- (i) a segmented shell (acetabular cup 2) having an interior surface;
- (ii) a second shell (intermediate element 3) fixedly retained with said interior surface of said segmented shell;
- (iii) a cup (plastic insert 4), having an exterior surface *sized and configured to be fixedly retained* (emphasis added to functional language) in said second shell; and
- (iv) a shaft (Figure 1) having a first end and a second end, said first end of said shaft having a ball (see Figure 1) formed thereon that is received by said cup *for movement therein* (emphasis added to functional language).

Afriat et al. disclose acetabular cup 2 as comprising a plurality of longitudinally and transversely arcuate segments 7 pivotally engaging a base (polar cap P2). Said plurality of segments form a cup-shaped segmented shell (see Figures 1-3).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyde, Jr. (US 6,589,281 B2) in view of Grimes (WO 00/48535 A1; previously cited in PTO-892).

Hyde, Jr. discloses the invention as claimed in claims 1, 5, and 8. Although Hyde, Jr. discloses the desirability of preventing/removing wear debris and introducing therapeutic agents into the joint area (something which is well known in the art), he/she did not particularly disclose the stem or shaft as having a set of channels with a structure (i.e., a first main channel having dual open ends, a second main channel having an open end and a closed end; secondary channels interconnecting with one of the main channels) as disclosed in claims 10 and 11.

However, that structure is known in the art. For example, Grimes discloses a joint prosthesis comprising a shaft having: (i) at least one tube (primary channel 616) having first and second open ends and extending from the bottom surface of said body and opening through said neck (see Figures 29 and 30); (ii) a second tube (primary channel 614) having an open end extending from the bottom surface of said body and a second closed end (see Figures 29 and 30); and secondary tubes (secondary channels 635-639) passing through a side wall of said body and through said second tube such that said secondary tubes are in fluid communication with said second tube in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area (see Figures 29 and 30; see page 46, lines 7-24; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teachings of a joint prosthesis stem/shaft having at least one tube having first and second open ends, a second tube having an open end and a second closed end, and secondary tubes passing through a side wall of said body

and through said second tube, as taught by Grimes, with the joint prosthesis shaft/stem of Hyde, Jr., in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area.

With regards to Applicant's argument "Grimes fails to establish prima facie obviousness", Grimes clearly states at page 30, lines 22-24 the desirability of total hip replacement comprising preparing the acetabulum in order to receive a prosthetic socket (acetabular cup). One of ordinary skill in the art would have been left to devise or select an appropriate acetabular cup.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afriat et al. (WO 01/35873 A1; also published as US 6,811,569 B1) in view of Grimes (WO 00/48535 A1; previously cited in PTO-892).

Afriat et al. disclose the invention as claimed in claims 1, 2, and 5. Although Afriat et al. disclose the desirability of preventing/removing wear debris and introducing therapeutic agents into the joint area (something which is well known in the art), he/she did not particularly disclose the stem or shaft as having a set of channels with a structure (i.e., a first main channel having dual open ends, a second main channel having an open end and a closed end; secondary channels interconnecting with one of the main channels) as disclosed in claims 10 and 11.

However, that structure is known in the art. For example, Grimes discloses a joint prosthesis comprising a shaft having: (i) at least one tube (primary channel 616) having first and second open ends and extending from the bottom surface of said body and opening through said neck (see Figures 29 and 30); (ii) a second tube (primary channel 614) having an open end extending from the bottom surface of said body and a second closed end (see Figures 29 and 30);

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and secondary tubes (secondary channels 635-639) passing through a side wall of said body and through said second tube such that said secondary tubes are in fluid communication with said second tube in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area (see Figures 29 and 30; see page 46, lines 7-24; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teachings of a joint prosthesis stem/shaft having at least one tube having first and second open ends, a second tube having an open end and a second closed end, and secondary tubes passing through a side wall of said body and through said second tube, as taught by Grimes, with the joint prosthesis shaft/stem of Afriat et al., in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area.

With regards to Applicant's argument "Grimes fails to establish prima facie obviousness", Grimes clearly states at page 30, lines 22-24 the desirability of total hip replacement comprising preparing the acetabulum in order to receive a prosthetic socket (acetabular cup). One of ordinary skill in the art would have been left to devise or select an appropriate acetabular cup.

Allowable Subject Matter

13. Claims 3, 4, 9, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Besemer et al. (US 5,879,401), Afriat et al. (US 6,811,569), and Chauvin (EP 610146).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

June 29, 2005



David H. Willse
Primary Examiner